Liza M. Walsh
Tricia B. O'Reilly
Eleonore Ofosu-Antwi
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217

E. Anthony Figg
C. Nichole Gifford
Lisa N. Phillips
Brett A. Postal
ROTHWELL, FIGG, ERNST & MANBECK
607 14th Street, NW, Suite 800
Washington, DC 20005
(202) 783-6040 (telephone)
(202) 783-6031 (facsimile)

Attorneys for Defendants Actavis Laboratories FL, Inc., Andrx Corp., Actavis, Inc., and Actavis Pharma, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIPHER PHARMACEUTICALS, INC., GALEPHAR PHARMACEUTICAL RESEARCH, INC., RANBAXY, INC., and RANBAXY PHARMACEUTICALS, INC. Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., ANDRX CORP., ACTAVIS, INC. and ACTAVIS PHARMA, INC. Defendants.	Case No. 1:13-6502-JEI-AMD

DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

Defendants Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc. – Florida), Andrx Corp., Actavis, Inc. and Actavis Pharma, Inc. (collectively, "Actavis" or "Defendants") submit this Opening Claim Construction Brief pursuant to the Amended Scheduling Order.

I. INTRODUCTION

This Hatch-Waxman case involves two patents, U.S. Patents 8,367,102[1] (the "'102 patent") and 7,435,427 (the "'427 patent") (collectively, the "patents-in-suit"), which are listed in the FDA's Orange Book for the Absorica® product. Plaintiffs, Cipher Pharmaceuticals, Inc., Galephar Pharmaceutical Research, Inc., Ranbaxy, Inc. and Ranbaxy Pharmaceuticals, Inc. (collectively, "Plaintiffs"), have asserted infringement of claims 1-4, 6-9, and 13-17 of the '102 patent and claims 1-3, 7-15, and 17 of the '427 patent. Plaintiffs' allegations are based on Actavis' filing of Abbreviated New Drug Application ("ANDA") No. 20-5063 seeking approval from the U.S. Food and Drug Administration ("FDA") to market its product.

The '102 patent is a continuation[2] of the '427 patent and, thus, shares a similar specification with the '427 patent. The patents-in-suit are directed to oral pharmaceutical compositions of isotretinoin and methods for treatment using them. The parties dispute eight claim terms in total – seven of which are unique terms. As explained below, the patents-in-suit were poorly drafted, and, as a consequence, the claims contain several terms that fail to comply with the recently articulated indefiniteness standard established by the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014). That is, several of the claim terms at issue fail to inform, with reasonable certainty, those skilled in the art about the scope of

[1] The '102 patent is attached to the Declaration of Russell J. Mumper, Ph.D. in Support of Defendants' Opening Claim Construction Brief ("Mumper Dec.") as Exhibit A. Exhibits to the Declaration of Russell J. Mumper, Ph.D. are cited herein as "Mumper Ex. __."

[2] The face of the '102 patent lists the '102 patent as a *continuation-in-part* of the '427 patent. The specification, however, recites that the '102 patent is a *continuation* of the '427 patent.

the invention and are not amenable to construction. For the most part, Plaintiffs' constructions attempt to extend this ambiguity with proposed claim constructions that do little to provide further meaning to the terms. Rather, Plaintiffs' rely on vague and uninformative constructions that consist largely of the same words of the claim terms rearranged in a new order. These constructions do little, if anything, to address the problems a person of ordinary skill would have with comprehending the scope of the asserted claims of the patents-in-suit. With respect to the remaining terms that are capable of construction, Defendants' proposed claim constructions are consistent with how the terms would have been understood by a person of ordinary skill in the context of the specification and prosecution history as of the critical date. Thus, as discussed below, Actavis respectfully requests that the Court adopt its proposed claim constructions.

II. AGREED CONSTRUCTION OF CLAIM TERMS

As reflected in the Joint Claim Construction and Prehearing Statement, the parties agreed that the term "surfactant" means "an excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic." (Dkt. No. 71). Subsequently, the parties agreed that the term "glycerol macrogolglycerides" means "glycerol or glyceroyl macrogolglycerides are mixtures of monoesters, diesters and triesters of glycerol and monoesters and diesters of macrogol (also called polyethylene glycol)." Defendants respectfully request that the Court adopt these constructions.

III. CLAIM CONSTRUCTION LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (quotation omitted). The claim language is the starting point for any claim construction

analysis. *See id.* at 1314. Claim terms are given the ordinary and customary meaning "that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. "[A] a term's ordinary meaning must be considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history." *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094 (Fed. Cir. 2013) (citing *Phillips*, 415 F.3d at 1314). "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. Indeed, the public has a right to rely on the patentee's definitive statements made during prosecution. *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1347 (Fed. Cir. 1998).

IV. CLAIM TERMS IN DISPUTE

A. "Semi-Solid Preparation" ('102 Patent, Claims 1 and 4)[3]

Defendants propose that the claim term "semi-solid preparation" means "a semi-solid suspension, emulsion, microemulsion, self-emulsifying drug delivery system (SEDDS), or self-emulsifying microemulsion drug delivery system (SMEDDS)." Unlike Plaintiffs' construction of "a semi-solid composition," Defendants' construction is supported by the '102 patent.

1. Defendants' Proposed Construction is Consistent with the Specification and Claims of the '102 Patent

The term "semi-solid preparation" does not expressly appear in the specification of the '102 patent. It appears only in claims 1 and 4. While the specification does not expressly refer to the term "semi-solid preparation," a person of ordinary skill in the art would have understood that the term, within the context of the '102 patent, refers to semi-solid suspensions, emulsions, microemulsions, SEDDS, and SMEDDS. *See* Mumper Dec. ¶14.

[3] In the headings set forth herein, Defendants have identified each independent claim in which the claim term is first recited. To the extent that a claim term appears in any dependent claims, the term should also be construed in the dependent claims as well.

Defendants' construction is consistent with statements in the '102 patent specification. *Id.* at ¶15. The specification states that the alleged invention "may be a suspension, emulsion or microemulsion." Mumper Ex. A, 2:6-8.[4] The Detailed Description of the Invention in the patent reinforces this understanding. Mumper Ex. A, 3:6-7 ("The active ingredient may also be formulated as a suspension, emulsion or microemulsion."). Further, in detailing the alleged "advantages of the semi-solid formulations of the invention," the specification states that the systems of the alleged invention "may consist of suspension[s], emulsion[s], microemulsion[s], self-emulsifying drug delivery systems (SEDDS®) or self-emulsifying microemulsion drug delivery system[s] (SMEDDS®)." Mumper Ex. A, 3:43-46. As such, Defendants' proposed construction is supported by, and consistent with, the specification and claims of the '102 patent.

2. Plaintiffs' Proposed Construction is Not Consistent with the Specification and Claims of the '102 Patent

Plaintiffs' proposed construction, "a semi-solid composition," is inconsistent with the claims of the '102 patent, as the terms "composition" and "preparation" are not used interchangeably in the claims. A patent's claims' use of different terms suggests that the patentee intended a differentiation in the meaning of those terms. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996).

Both claim 1 and 4 of the '102 patent use the terms "composition" and "preparation" differently within a close proximity, clearly indicating that the terms have different meanings. *See* Mumper Dec. ¶16. For example, claim 1 recites, in relevant part, "a method of treating a skin disorder, which comprises a step of orally administering to a mammal having the skin

[4] The citation to Mumper Exhibit A (*i.e.*, the '102 patent) at 2:6-8 refers to column 2, lines 6-8 of the '102 patent. This citation format is used to cite to patents herein.

disorder, an oral pharmaceutical ***composition*** of isotretinoin, which comprises a semi-solid ***preparation***." Mumper Ex. A, claim 1 (emphasis added). Claim 4 of the '102 patent recites "the method of claim 1, wherein the ***composition*** comprises a semi-solid ***preparation***…" Mumper Ex. A, claim 4 (emphasis added). As these examples demonstrate, the term "preparation" is used to further define the "composition" of the claims. *See* Mumper Dec. ¶16. By their use of the inclusive transition term "comprising," the claims signal that the "composition" may include more than the "semi-solid preparation." *See Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997). Thus, the term "preparation" is used to further narrow the scope of the term "composition," and the two terms are not used interchangeably. *See* Mumper Dec. ¶16. As a result, a skilled person would have understood the terms to have different meanings – unlike Plaintiffs' proposed construction, which seeks to equate them. *See id.* Accordingly, Defendants' claim construction, not Plaintiffs', is consistent with the specification and claims of the '102 patent. Defendants' respectfully request that the Court adopt their proposed construction of the term "semi-solid preparation."

B. "Hydrophobic Lipidic Balance (HLB) value" ('102 Patent, Claim 1)

Defendants submit that the claim term "hydrophobic lipidic balance (HLB) value" fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention and is not amenable to construction. Plaintiffs' attempt to rewrite "*Hydrophobic Lipidic* Balance (HLB) value" as "*hydrophilic lipophilic* balance (HLB) value" is improper as it is a belated attempt to rewrite the claims and significantly (and impermissibly) alter their scope.[5]

Claim 1 of the '102 patent recites the term "hydrophobic lipidic balance (HLB) value."

[5] Should the Court adopt Plaintiffs' proposed construction, Defendants submit that the construction "hydrophilic lipophilic balance (HLB) value" is indefinite. *See infra* Section IV(C).

This term, however, does not appear in the '102 patent's specification.[6] Instead, in one instance, the '102 patent references a *different* HLB value, "the hydrophilic/lipophilic balance value (HLB)." Mumper Ex. A, 3:15-16. The specification, however, makes no suggestion that the "hydrophilic/lipophilic balance value (HLB)" is related to the "hydrophobic lipidic balance (HLB) value" recited in claim 1. *See* Mumper Dec. ¶18. Thus, there is nothing in the '102 patent that would have informed a skilled person that the term "hydrophobic lipidic balance (HLB) value" is synonymous with, or equivalent to, Plaintiffs' proposed claim construction of "hydrophilic lipophilic balance (HLB) value." *Id.* Further, a person of ordinary skill would not have understood the meaning of the term "hydrophobic lipidic balance (HLB) value" at the time of the invention. *See* Mumper Dec. ¶17. Due to the lack of clarity regarding this term, the scope of the claims would not have been reasonably certain to a person of ordinary skill.

Recognizing this problem, Plaintiffs have pursued a claim construction that would substantially rewrite the claims of the '102 patent. Such an attempt to have the Court rewrite the claims is improper for at least three reasons. *First*, it is not apparent from the face of the '102 patent that there is an error. *Second*, Plaintiffs' proposed construction would result in a substantial rewrite of the claims. *Third*, Plaintiffs' belated attempts to have this Court significantly rewrite the claims runs counter to 35 U.S.C. §§ 254 and 255 and the notice function of the patent system. Each of these reasons is addressed below in detail.

1. The Alleged Error in Claim 1 of the '102 Patent is not Apparent from the Face of the '102 Patent

The Supreme Court has held that, in a patent infringement suit, a district court can correct an obvious error in a patent claim. *See I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429

[6] While this term does not appear in the specification of the '102 patent, the terms "hydrophobic" and "lipidic" appear repeatedly in the specification of the '102 patent.

(1926). Such authority to correct an obvious error is not absolute, however, and "[a] district court can correct a patent only if, among other things, 'the error is evident from the face of the patent.'" *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1333 (Fed. Cir. 2014) (quoting *Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1303 (Fed. Cir. 2005)). Even where the prosecution history clearly indicates to a person of ordinary skill that an error is present in a claim, if the error is not evident from the face of the patent, a district court cannot correct it. *See H-W Tech., L.C.*, 758 F.3d at 1334; *see also Group One, Ltd.*, 407 F.3d at 1302-03.

It is not apparent from the face of the '102 patent that there is an obvious error in claim 1. Claim 1 of the '102 patent is not clearly missing a word, as was the case in other instances where the Federal Circuit held that an error was apparent from the face of the patent. *See CBT Flint Partners, LLC v. Return Path, Inc.*, 654 F.3d 1353, 1360 (Fed. Cir. 2011) (holding that the phrase "detect analyze" in one of the claims of the issued patent was clearly missing the conjunction "and"). Rather, claim 1 of the '102 patent uses terms (*e.g.*, "hydrophobic" and "lipidic") that are used throughout the specification of the '102 patent and would have been readily understood by a person of ordinary skill in the art. *See* Mumper Dec. ¶19. Thus, a person of ordinary skill in the art would have determined that the patentees' use of these terms that appear frequently in the specification was intended. *Id.*

The prosecution history does not provide a clear indication that the claim term "Hydrophobic Lipidic Balance (HLB) value" is an error that should have read "hydrophilic lipophilic balance (HLB) value."[7] To the contrary, the fact that the term was carried through

[7] During prosecution of the '102 patent, the Applicants initially drafted claims reciting "at least one of [the at least two lipidic excipients] being *hydrophilic* having a *Hydrophilic* Lipidic Balance (HLB) value…" Mumper Ex. D, claim 14 (emphasis added). In a subsequent amendment, the claim was revised to recite "at least one of [the at least two lipidic excipients] being *hydrophobic* having a *Hydrophobic* Lipidic Balance (HLB) value…" Mumper Ex. E,

multiple amendments indicates that it was intentional rather than a mistake. Even if the prosecution history did provide evidence suggesting that the term "Hydrophobic Lipidic Balance (HLB) value" was an error, this would not provide a basis for the Court to rewrite the claims. *See H-W Tech., L.C.*, 758 F.3d at 1333.

2. Plaintiffs' Construction Would Result in a Significant Rewriting of the Claim Scope of the '102 Patent, Which is Outside of the Scope of Errors that a District Court is Permitted to Correct

"[A] district court can act to correct an error in a patent by interpretation of the patent where no certificate of correction has been issued…only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed. Cir. 2003). Neither condition is met here. *See supra* n. 5. Further, while a district court can "correct obvious minor typographical and clerical errors in patent," it cannot correct "major errors." *Id.* at 1357; *see also Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1353 (Fed. Cir. 2009) ("[C]ourts cannot 'rewrite claims to correct material errors," but rather, "a court can correct an obvious typographical error."); *see also Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, n.1 (Fed. Cir. 2003) ("Bridgeport argues that the claim term should be 'base end'…because the

---

claim 14 (emphasis added). Plaintiffs may argue that these portions of the prosecution history indicate that the phrase "Hydrophobic Lipidic Balance (HLB) value" is a typographical error. The term "lipidic," however, appears in the first set of claims as well as the later claims. Thus, there is nothing in the prosecution history indicating that including the word "lipidic," instead of "lipophilic," was an error. Additionally, the Notice of Allowance does not shed light on this issue. In the Notice of Allowance, the Examiner noted that the term "hydrophobic" in the claim – referring to the word "hydrophobic" that appears after the word "being" in the claims, not the word in the term "Hydrophobic Lipidic Balance (as evidenced by, *inter alia*, the wording of the issued claims) –should be amended to "hydrophilic." *See* Mumper Ex. G. Even if the prosecution history supported the position that the word "hydrophobic" was intended to recite "hydrophilic," there is no indication that the word "lipidic" was a typographical error.

word 'and' following 'base' in Claim 1 is allegedly a typographical error introduced by the PTO. We must take the claim as we find it, however."). Claims that require corrections that are substantively significant and require guesswork as to what was intended by the patentee in order to make sense of the patent claim are not properly the subject of correction by the court. *CBT Flint Partners, LLC*, 654 F.3d at 1358. Such is the case here with the correction suggested *via* claim construction.

Plaintiffs' attempt to rewrite the term "*Hydrophobic Lipidic* Balance (HLB) value" to "*hydrophilic lipophilic* balance (HLB) value" is a substantively significant rewriting of the claims. Specifically, the term "hydrophobic," which roughly translates to "water fearing," is the exact opposite of the term "hydrophilic," which roughly translates to "water loving." *See* Mumper Dec. ¶20. Moreover, the term "lipophilic" is not synonymous with the term "lipidic." *See id.* at ¶21. Indeed, "lipophilic" refers to the physical and chemical nature of a compound that *dissolves in* lipids or fats, and "lipidic" means a lipid or fat. *Id.*

Furthermore, construing the term "Hydrophobic Lipidic Balance (HLB) value" to mean "hydrophilic lipophilic balance (HLB) value" would significantly alter the scope of the claims. The term "Hydrophobic Lipidic Balance (HLB) value" is a significant limitation in claim 1, as it is used as a basis for defining one of the at least two lipidic excipients set forth in claim 1 of the '102 patent. As every dependent claim in the '102 patent depends from claim 1, the construction of this term has a bearing on every asserted claim of the '102 patent. Therefore, Plaintiffs' proposed construction is an improper attempt to rewrite all of the claims of the '102 patent.

3. Plaintiffs' Construction Would Run Counter to Statutory Provisions

If Plaintiffs truly contend that the term "Hydrophobic Lipidic Balance" is an error, the proper course to correct such an error is *via* a certificate of correction. Tellingly, Plaintiffs have

not sought a certificate of correction through the United States Patent and Trademark Office ("PTO"), but instead have attempted to circumvent certain provisions of the statutory provisions relating to such corrections. Section 254 of the Patent Statute provides the PTO with authority to issue a certificate of correction to correct a mistake in a patent incurred as a result of PTO error. Similarly, 35 U.S.C. § 255 provides the PTO with authority to issue a certificate of correction to correct "a mistake of a clerical or typographical nature, or of minor character, which was not the fault of the Patent and Trademark Office" wherein "a showing has been made that such mistake occurred in good faith." Both statutory provisions make clear that the certificate of correction is only effective to all litigations commenced ***after the date of issuance of the certificate of correction***. *See* 35 U.S.C. §§ 254, 255.

Plaintiffs' attempt to have this Court rewrite the claims of the '102 patent *via* claim construction, and apply those corrections retroactively, would effectively circumvent the statutorily mandated Congressional intent behind it. *See Novo Indus., L.P.*, 350 F.3d at 1357. That is, Plaintiffs are seeking to have what they contend to be a substantial error in the patent retroactively corrected by this Court, because Plaintiffs could not seek such relief from the PTO. *Id.* Not only would such a result run counter to 35 U.S.C. §§ 254 and 255, it would run counter to the notice function of patents. One of the fundamental functions of the patent system is to put the public on notice of the scope of issued patents. *See H-W Tech., L.C.*, 758 F.3d at 1335. Allowing Plaintiffs to substantially rewrite a claim during litigation would deprive Defendants of the right to be informed of the scope of the claims prior to litigation. Therefore, statutory and policy considerations support finding against Plaintiffs' proposed construction. In view of the above, Defendants respectfully request that the Court find that the term "hydrophobic lipidic balance (HLB) value" is not amenable to construction.

C. "Having a[n] HLB Value Equal to or Greater Than 10" and "Has an HLB Value of At Least [12, 13]" ('427 Patent, Claims 1, 2, 3, 15, and 17)[8]

Defendants submit that the claim terms "having a[n] HLB value equal to or greater than 10" and "has an HLB value of at least 12, 13" are not amenable to construction. Where there are different measures for determining a claim element, and the patent specification and prosecution history do not provide guidance as to which measure is referenced in the claims of the patent, the claims are invalid as indefinite. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 723 F.3d 1363 (Fed. Cir. 2013), *cert. granted*, 134 S. Ct. 1761 (2014) (holding that the term "having a molecular weight of about 5 to 9 kilodaltons" was indefinite where a person of ordinary skill would have used three different measures to determine molecular weight). Similarly, when a claim recites a property that can be calculated or determined using various methods and the patent and prosecution history do not provide guidance as to which method the claims refer to, the claims are invalid as indefinite. *See Honeywell Int'l, Inc. v. ITC*, 341 F.3d 1332 (Fed. Cir. 2003) (holding that the term "melting point elevation" ("MPE") was indefinite where there were multiple ways to prepare a sample to determine the MPE and the specification and prosecution history did not provide any guidance).

Numerous methods for determining the hydrophilic lipophilic balance value of an excipient existed as of the critical date of the '102 patent, including, for example, the Griffin method, Davies method, H-NMR method and dielectric constant method. *See* Mumper Dec. ¶¶51-55; Mumper Ex. S; Mumper Ex. T; Mumper Ex. V. The claims, specification, and prosecution history do not provide any guidance as to which method is intended by the claims.

[8] To the extent that the Court adopts Plaintiffs' proposed construction of "Hydrophobic Lipidic Balance (HLB) value" from independent claim 1 of the '102 patent as "hydrophilic lipophilic balance (HLB) value," *see supra* Section IV(B), Defendants submit that the term is indefinite for the reasons discussed in this section.

See Mumper Dec. ¶51. Further, no single methodology was universally used in the pharmaceutical arts to determine the hydrophilic lipophilic balance value of an excipient. *See id.* The various methods used for determining hydrophilic lipophilic balance values include theoretical methods based on various formulas. *See id.*; Mumper Ex. T at 250; Mumper Ex. V at 20. Each formula includes different variables, and thus, these different formulas produce different hydrophilic lipophilic balance values. *See* Mumper Dec. ¶51; *see also* Mumper Ex. S at 30. Additionally, these formulas have several drawbacks and several of them lack precision. *See* Mumper Ex. S at 30 ("[S]ome authors discussed and criticized the HLB scales claiming them to be imprecise, empirical, indirect and unsuitable for every surface-active agents.") (internal citations omitted); Mumper Ex. U at 115; *see also* Mumper Dec. ¶53.

In addition to theoretical methods, there are also several different experimental methods for determining a hydrophilic lipophilic balance value. *See* Mumper Ex. S; Mumper Dec. ¶55. These experimental methods can also produce different results. *See* Mumper Dec. ¶55. Furthermore, the experimental methods have different protocols that can produce differing results, as the hydrophilic lipophilic balance value determination is effected by several different parameters. *See* Mumper Ex. U at 115 ("[T]he HLB of an emulsifier is influenced by experimental conditions such as types of oils, additives to water or oil, emulsifier concentration, phase volume of the oil, and temperature, or even by the procedure for preparing an emulsion.") (internal citations omitted); Mumper Ex. W at 276; Mumper Dec. ¶55.

Thus, a person of ordinary skill would have recognized that there are multiple different methodologies for determining a hydrophilic lipophilic balance value. *See* Mumper Dec. ¶¶51-55. Further, a person of ordinary skill in the art would have recognized that the method that was used to calculate or experimentally determine the hydrophilic lipophilic balance value would

influence the determined value. *See id.* The claims, specifications of the patents-in-suit, and prosecution history, however, do not provide any discussion or guidance regarding the hydrophilic lipophilic balance method. *See id.* ¶56.

Instead, the claims merely recite limitations requiring certain hydrophilic lipophilic balance values devoid of any mention of whether these values should be calculated or derived using a certain formula or experimental procedure. Likewise, the specification refers to hydrophilic lipophilic balance values without any mention of the method that should be used to determine the hydrophilic lipophilic balance values. *See, e.g.*, Mumper Ex. B, Abstract. During prosecution, the Applicants did not provide any guidance as to the meaning of the hydrophilic lipophilic balance values recited in the claims. Thus, the reference to hydrophilic lipophilic balance values in the claims fails to inform, with reasonable certainty, a person of ordinary skill as to the scope of the claims, as required by the Supreme Court. *See Nautilus, Inc.*, 134 S. Ct. at 2124. Further, as in *Teva Pharms. USA*, the ambiguity in the values for hydrophilic lipophilic balance in the claims cannot be resolved, as there are different measures for determining a claim element and the patent specification and prosecution history do not provide guidance as to which measure is to be used. 723 F.3d at 1368. Therefore, the claims are invalid as indefinite. *Id.* Defendants respectfully request that the Court hold that the claim terms "having a[n] HLB value equal to or greater than 10" and "has an HLB value of at least 12, 13" are indefinite.

D. "The Isotretinoin is Partially in Solution and/or Partially in Suspension" ('102 Patent, Claim 4)

Defendants submit that the claim term "the isotretinoin is partially in solution and/or partially in suspension" is indefinite. The claim term contains the phrase "and/or." The combination adjunctive-disjunctive conjunction in the claim term results in the following two alternatives: (1) the isotretinoin is partially in suspension ***and*** partially in solution; and (2) the

isotretinoin is partially in suspension ***or*** partially in solution. A person of ordinary skill would not be able to ascertain the scope of the claim because the claim language encompasses instances in which the isotretinoin is partially dissolved (in solution) (but the remainder is neither dissolved nor suspended) and instances in which the isotretinoin is partially suspended (but the remainder is neither dissolved nor suspended). *See* Mumper Dec. ¶28. In both of these instances the implication is that, the portion of the isotretinoin that is neither dissolved nor suspended would be as a solid portion that exists as an unsuspended lump in the formulation. *See id.* at ¶29. Such a construction would make no sense in the context of the disclosure, because the undissolved, unsuspended lump of isotretinoin would serve no purpose and the formulation would not be pharmaceutically acceptable. *See id.*

1. "The Isotretinoin is Partially in Solution and/or Partially in Suspension" is Not Amenable to Construction

Defendants submit that the portion of the claim directed to the isotretinoin being partially in solution *or* partially in suspension would not be reasonably certain to a person of ordinary skill. A skilled person would understand, and Plaintiffs do not appear to dispute based on their proposed claim construction, that isotretinoin partially in suspension refers to isotretinoin that is partially undissolved, while isotretinoin that is partially in solution refers to isotretinoin that is dissolved. That is, the portion of the claim term referring to isotretinoin partially in suspension refers to a dispersion in which the isotretinoin is partially undissolved in the at least two lipidic excipients. *See* Mumper Dec. ¶¶25-26. Further, the portion of the claim term referring to isotretinoin partially in solution refers to a dispersion in which the isotretinoin is partially dissolved in the at least two lipidic excipients. *See id.* at ¶27; *see also* Mumper Ex. A, 3:5-6 ("The isotretinoin may be solubilized in the mix of excipients or partially solubilized.").

With respect to the alternative portion of the claim term providing that the isotretinoin is

partially in suspension *or* partially in solution, the claim term requires that the isotretinoin satisfies ***one and only one*** of these conditions. The term "or" is exclusive and provides for the inclusion of one alternative but not both. *See SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1199 (Fed. Cir. 2013); *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1331 (Fed. Cir. 2001). Further, in the context of claim 4, the recitation of the conjunction "and" accounts for the alternative where the isotretinoin is partially dissolved *and* partially undissolved, thus the conjunction "or" must mean something else. *See Ethicon Endo-Surgery, Inc.*, 93 F.3d at 1579. Based on the relevant case law, the "or" portion of the claim term must mean that the isotretinoin is partially in suspension *or* partially in solution, but not partially in suspension *and* partially in solution. Therefore, a portion of the isotretinoin must be neither in solution nor in suspension.

A person of ordinary skill would not have been able to ascertain with reasonable certainty the scope of the claim wherein the isotretinoin is partially dissolved, but the remaining isotretinoin is not partially undissolved. *See* Mumper Dec. ¶29. Likewise, a person of ordinary skill would not have been able to ascertain with reasonable certainty the scope of the claim wherein the isotretinoin is partially undissolved, but the remaining isotretinoin is not partially dissolved. *See id*. The '102 patent does not indicate that isotretinoin can be in a state other than dissolved or undissolved. *See* Mumper Ex. A. Furthermore, a skilled person would not have known what other state isotretinoin could be in – other than partially in suspension or partially in solution. *See* Mumper Dec. ¶29. Therefore, a person of ordinary skill would not be able to ascertain with reasonable certainty the scope of the asserted claims of the '102 patent. *See id*.

2. Plaintiffs' Proposed Construction Improperly Attempts to Read the Word "Partially" Out of the Claims

Plaintiffs' proposed construction, "a preparation in which the isotretinoin is partially in suspension wherein at least some particles of isotretinoin are not dissolved and/or is partially in

solution wherein at least some particles of isotretinoin are dissolved," is improper as it attempts to read the term "partially" out of the claims. In specifying that "partially in suspension" provides that *at least some particles* of isotretinoin are not dissolved, Plaintiffs' construction allows for the possibility that *all* particles of isotretinoin are not dissolved. *See* Mumper Dec. ¶31. Likewise, in specifying that "partially in solution" provides that *at least some particles* of isotretinoin are dissolved, Plaintiffs' construction allows for the possibility that *all* particles of isotretinoin are dissolved. *Id.* "[T]he ordinary and customary meaning of the term 'partially' excludes 'totally.'" *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008). Further, the '102 patent specification recognizes the distinction between being partially solubilized and entirely solubilized. *See* Mumper Ex. A, 3:5-6 ("The isotretinoin may be solubilized in the mix of excipients or partially solubilized."); Mumper Ex. A, 5:13-33. Therefore, Plaintiffs' proposed construction of "the isotretinoin is partially in suspension and/or partially in solution" is improper because it reads "partially" out of the claims.

Thus, the claim term "the isotretinoin is partially in solution and/or partially in suspension" is indefinite. However, if the Court were to determine that the claim term is amenable to construction, Defendants respectfully submit that the most logical construction is "(1) a dispersion in which the isotretinoin is partially undissolved and partially dissolved in the at least two lipidic excipients; or (2) a dispersion in which the isotretinoin is partially undissolved in the at least two lipidic excipients or the isotretinoin is partially dissolved in the at least two lipidic excipients, and the remaining isotretinoin is neither in suspension nor in solution." Such a construction is consistent with how a person of ordinary skill would have understood this claim term. *See* Mumper Dec. ¶30.

E. "Semi-Solid Suspension" ('102 Patent, Claim 13; '427 Patent, Claim 1)

Defendants submit that the claim term "semi-solid suspension" means "a semi-solid composition in which isotretinoin is predominantly undissolved and is dispersed in the at least two lipidic excipients" for at least three separate and legally sufficient reasons. *First*, Defendants' proposed construction is consistent with how a person of ordinary skill would have understood the term and properly places it in the context of the claims, specification and prosecution history. *Second*, Defendants' proposed construction is consistent with other claims – both issued and cancelled – from the patents-in-suit. *Third*, Defendants' proposed construction – unlike Plaintiffs' proposed construction – does not impermissibly attempt to reclaim subject matter that was disclaimed during prosecution.

1. Defendants' Proposed Construction is Consistent with the Content of the '102 Patent Claims, Specification and Prosecution History

A person of ordinary skill in the art would have understood that a suspension refers to a composition in which isotretinoin is predominantly undissolved and is dispersed in the at least two lipidic excipients. *See* Mumper Dec. ¶32. This proposed construction – in contrast to Plaintiffs' proposed claim construction, "a semi-solid composition wherein the preparation is in the form of a suspension" – provides an explanation of the claim language as it would have been understood by a person of ordinary skill, as opposed to merely rearranging the words of the claim. *See Terlep v. Brinkmann Corp.*, 418 F.3d 1379, 1382 (Fed. Cir. 2005) ("The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims."). As would be understood by a person of ordinary skill, a suspension has two key properties: (1) the word "suspension" indicates that one component is predominantly undissolved in the remaining components; and, (2), the word "suspension" indicates that the composition is a dispersion. *See* Mumper Dec. ¶¶33-36.

First, the word "suspension" as used in the art of pharmaceutics refers to a composition in which a solid component is undissolved in the remaining components. *See* Mumper Dec. ¶33; *see also* Mumper Ex. H at 477 (defining a suspension as "a coarse dispersion in which ***insoluble solid particles*** are dispersed in a liquid medium") (emphasis added); Mumper Ex. I at 1542 (defining a suspension as "a preparation of finely divided, ***undissolved drug*** dispersed in a liquid vehicle") (emphasis added). The term "suspension" is in contrast to the term "solution," which refers to a composition in which a component is dissolved in the remaining components. *See* Mumper Dec. ¶34; *see also* Mumper Ex. I at 1521 (defining a solution as "a homogeneous mixture that is prepared by ***dissolving*** a solid, liquid or gas in another liquid and represents a group of preparations in which the molecules of the solute or dissolved substance are dispersed among those of the solvent") (emphasis added).

There can be no dispute that the term suspension requires the isotretinoin to be undissolved, as Plaintiffs' construction of "the isotretinoin is partially in suspension" provides that "the isotretinoin is partially in suspension wherein *at least some particles of isotretinoin are not dissolved*." (emphasis added). That is, in construing the term "suspension" in a different claim term, Plaintiffs acknowledge that the term requires that isotretinoin is "not dissolved." Such a construction is consistent with the specification, which discusses the term suspension in the context of the state of the isotretinoin in relation to the two lipidic excipients. *See, e.g.*, Mumper Ex. A, 3:5-6, Mumper Ex. B, 2:62-64 ("The isotretinoin may be solubilized in the mix of excipients or partially solubilized."); Mumper Ex. A, 5:16-18; Mumper Ex. B, 5:12-15 ("The molten mix of these two excipients allows to totally or partially…dissolve isotretinoin.").

Furthermore, the term "suspension" requires that the isotretinoin be predominantly undissolved in the at least two lipidic excipients. *See* Mumper Dec ¶35. A person of ordinary

skill would have understood that a suspension would not encompass a composition in which only a minor portion of the isotretinoin was undissolved in the at least two lipidic excipients. *See id.* at ¶35. While a formulation in which only a minor portion of drug particles are undissolved might be referred to as a "solution" or might be characterized as "partially suspended," a "suspension" formulation is one in which the particles are insoluble and all or almost all of them are suspended and dispersed uniformly throughout the formulation. *See id.* at ¶34. Further, as set forth in *Martin's Physical Pharmacy*, a suspension is "a coarse dispersion in which ***insoluble*** solid particles are dispersed in a liquid medium." Mumper Ex. H at 477 (emphasis added). The reference to the word "insoluble" indicates that a majority, not a small portion, of the solid particles are dispersed in the liquid medium – otherwise the particles would not be insoluble but rather would be very slightly soluble in the liquid medium. *See* Mumper Dec. ¶35. Rather, a person of ordinary skill would have understood that a composition in which a majority of the isotretinoin was dissolved and only a minority of the isotretinoin was undissolved in the at least two lipidic excipients would be a solution not a suspension. *See id.*

Second, a person of ordinary skill would have understood that a suspension refers to a composition in which the undissolved isotretinoin is dispersed in the lipidic excipients. *See* Mumper Dec. ¶36. The patents-in-suit recognize that a suspension is a dispersion system. *See* Mumper Ex. A, 6:20-23; Mumper Ex. B, 6:25-29 ("The use of dispersed systems (emulsions or suspensions) instead of only lipophilic or hydrophilic vehicles improves the absorption of the drug as well as increasing a larger contact surface."). Extrinsic evidence further supports the fact that a suspension requires a dispersion. *See* Mumper Dec. ¶36; Mumper Ex. H at 477 (defining a suspension as "a coarse dispersion in which insoluble solid particles are ***dispersed*** in a liquid medium") (emphasis added); Mumper Ex. I at 1542 (defining a suspension as "a preparation of

finely divided, undissolved drug ***dispersed*** in a liquid vehicle") (emphasis added). Thus, a skilled person would have understood that a suspension refers to a composition in which isotretinoin is predominantly undissolved in the at least two lipidic excipients.

2. Defendants' Proposed Construction is Consistent with Other Claims of the Patents-in-Suit

Unlike Plaintiffs' proposed construction, Defendants' construction is consistent with other claims of the patents-in-suit and their prosecution histories. *See* Mumper Dec. ¶36. The patentee drafted other claims (both that issued and were cancelled) that were directed to embodiments in which the isotretinoin is not predominantly in suspension. Claim 4 of the '102 patent states "the isotretinoin is partially in suspension." Based on this, it is clear that the patentee knew how to draft a claim that encompassed a composition wherein the isotretinoin was ***partially*** in suspension as opposed to predominantly in suspension. *See id.* at ¶37.

Furthermore, during prosecution of the '427 patent, the patentee pursued claims that were directed to "a semi-solid suspension or solution or both." *See* Mumper Ex. J, claim 14. In drafting claim 14, it is clear that the inventors considered a composition that was both a semi-solid suspension and solution to be different than a semi-solid suspension. *See also Ethicon Endo-Surgery, Inc.*, 93 F.3d at 1579 (holding that the use of different terms in a claim suggests that the patentee intended the use of different terms to reflect a differentiation in the meaning of those terms). Unlike the proposed claim cancelled during prosecution, the issued claims in the patents-in-suit are not directed to both a semi-solid suspension and solution, but, rather, the claims are directed to a semi-solid suspension. *Compare* Mumper Ex. J, claim 14 *with* Mumper Ex. B, claim 1. When a patentee shows that it knows how to draft a claim of a certain claim scope, but uses different claim terms, it is presumed that the difference is meaningful. *See IGT v. Bally Gaming Int'l, Inc.*, 659 F.3d 1109, 1116 (Fed. Cir. 2011) ("IGT also notes that Bally

ignores claim 21 of the ′812 patent that states the command is sent to 'only one' gaming device. It argues that this shows that the applicants knew how to claim a 'one and only one' embodiment and that the word 'one' should not be so limiting. . . . We agree with IGT."); *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 807 (Fed. Cir. 2007) ("The intrinsic evidence of the specification therefore suggests that the patentees knew how to restrict their claim coverage to holes passing through at right angles. They could have used the word 'perpendicular,' as they did in discussing their preferred embodiment. Instead, they chose a different term."). Thus, it is clear that the scope of the term "semi-solid suspension" excludes compositions having both semi-solid suspensions (*i.e.*, compositions with isotretinoin partially undissolved) and semi-solid solutions (*i.e.*, compositions with isotretinoin partially dissolved). Rather, the claims require that the isotretinoin be predominantly undissolved in the at least two lipidic excipients.

3. Plaintiffs Disclaimed Subject Matter Directed to Both a Semi-Solid Suspension and Semi-Solid Solution With Respect to the '427 Patent

During prosecution of the '427 patent, the Applicants disclaimed subject matter directed to compositions having both a semi-solid suspension and a semi-solid solution. That is, the Applicants disclaimed subject matter directed to a composition in which the isotretinoin is both dissolved and undissolved. *See* Mumper Ex. L at 14. During prosecution of the '427 patent, the patentee initially pursued claims that were directed to a semi-solid suspension or solution or both. *See* Mumper Dec. ¶38; Mumper Ex. J, claim 14. The PTO, however, rejected these claims as obvious under 35 U.S.C. § 103(a). *See* Mumper Ex. L. Specifically, the Examiner alleged that the pending claims were obvious over United States Patent No. 5,993,858 to Crison et al. in view of United States Patent No. 6,267,985 to Patel et al. ("Patel '985"). *Id.*

In response to the Examiner's rejection, the Applicants amended the pending claims to narrow the scope of the claims to recite only "a semi-solid suspension," as opposed to "a semi-

solid suspension or solution or both." *See* Mumper Dec. ¶39. In the remarks to the Examiner's objections, the Applicants stressed the narrow scope of the claims by stating "[s]pecifically, present main composition claim 14 recites 'an oral pharmaceutical of Isotretinoin having increased bioavailability, which comprises a semi-solid suspension…" *See* Mumper Ex. L at 13 (emphasis in original). The Applicants' amendment narrowing the scope of the claims was made to distinguish the art cited by the Examiner during prosecution. *See* Mumper Dec. ¶39. With regard to the Patel '985 reference, the Applicants' remarks distinguished this reference by arguing that it "merely discloses a clear, aqueous dispersion-based composition, which may contain isotretinoin as an active ingredient." *See id.*; Mumper Ex. L at 14. The Patel '985 reference discloses compositions wherein "a therapeutic agent is capable of being solubilized in the triglyceride, the carrier, or both the triglyceride and the carrier." *See* Mumper Ex. K, claim 1. That is, the Patel '985 reference discloses compositions wherein the therapeutic agent (*e.g.*, isotretinoin) is in a solution. *See* Mumper Dec. ¶39. Therefore, during prosecution, the Applicants amended the scope of the claims of the '427 patent and excluded semi-solid solutions in an attempt to distinguish the prior art including, at least, the Patel '985 reference. *Id.*

Because the Applicants disclaimed subject matter directed to semi-solid solutions or both semi-solid suspensions and semi-solid solutions, the issued claims cannot be construed to include that subject matter. The Supreme Court has recognized that a patentee cannot reclaim subject matter that was eliminated during prosecution of the patent. *See Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-21 (1940) ("It is a rule of patent construction consistently observed that a claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected, and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent."). In following this

precedent, the Federal Circuit has recognized the doctrine of prosecution history disclaimer, which forbids a patentee from later reclaiming subject matter that was narrowed during prosecution. *See Elekta Instrument S.A. v. O.U.R. Scientific Int'l*, 214 F.3d 1302, 1308 (Fed. Cir. 2000) ("Claims that have been narrowed in order to obtain issuance over the prior art cannot later be interpreted to cover that which was previously disclaimed during prosecution."). Plaintiffs' proposed construction would violate this fundamental claim construction principle because it does not exclude subject matter directed to both a semi-solid suspension and a semi-solid solution. *See id*. Defendants' proposed construction, on the other hand, accounts for this subject matter disclaimer and requires that the term "semi-solid suspension" only encompasses compositions wherein the isotretinoin is predominantly undissolved in the at least two lipidic excipients. Therefore, Defendants respectfully request that the Court reject Plaintiffs' proposed construction and adopt Defendants' proposed construction of the term "a semi-solid suspension."

F. "An Amount of About 1 to 10% of At Least One Additional Surfactant" and "About 1-10% of an Additional Surfactant" ('427 Patent, Claims 1 and 12)

Defendants submit that the claim terms "an amount of about 1 to 10% of at least one additional surfactant[9]" and "about 1-10% of an additional surfactant" are indefinite. *First*, the term "additional surfactant" is indefinite because the claim does not recite an initial or first surfactant. Thus, a person of ordinary skill would be unable to determine the meaning of the word "additional." *Second*, the terms "about 1 to 10%" and "about 1-10%" are not supported by the specification and are indefinite. While Defendants submit that these terms are indefinite, if the terms were construable, the most logical meaning would be "an amount of 0.95% to 10.50% of at least one additional excipient that can reduce the interfacial tension between two immiscible

[9] The parties do not dispute the meaning of the term "surfactant" as used in these claim terms. *See supra* Section II.

phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic," rather than Plaintiffs' proposed construction – "an amount of approximately 1 to 10% of at least one additional surfactant."

1. The Term "Additional Surfactant" is Not Amenable to Construction

The terms "an amount of about 1 to 10% of at least one additional surfactant" and "about 1-10% of an additional surfactant" fail to inform, with reasonable certainty, a person of ordinary skill in the art as to the scope of the claims, because a person of ordinary skill would not have been able to determine the meaning of the term "additional surfactant." The '427 patent does not provide any guidance as to the meaning of the term "additional surfactant," which clearly implies that the formula contains at least one other surfactant. The term "additional surfactant" does not appear anywhere outside of the claims. Additionally, the '427 patent specification does not expressly refer to a "first" surfactant or an "initial" surfactant. Instead, the specification merely provides that the compositions may contain "at least one surfactant." *See* Mumper Ex. B, 4:36-37 ("For example, the composition contains from 1 to 10% by weight of at least one surfactant."). This disclosure, however, does not provide any guidance as to the meaning of the term "additional surfactant." *See* Mumper Dec. ¶42. Moreover, the specification characterizes the examples disclosed in the specification as including a surfactant – not an *additional* surfactant. For example, formulation F2 in the specification is described as a "suspension with surfactant." *See* Mumper Ex. B, 9:50-55. Thus, it is clear that the '427 patent does not provide any guidance as to the meaning of the term "additional surfactant." *See* Mumper Dec. ¶42.

Furthermore, a person of ordinary skill would have considered that the term "additional surfactant" to be indefinite and as failing to apprise the public of the scope of the claims with reasonable certainty. Specifically, a skilled person would not have been able to ascertain

whether the term "additional" means that one of the previous enumerated excipients must be a surfactant or the term "additional" requires the presence of at least two surfactants. *See* Mumper Dec. ¶42. Therefore, the term "additional surfactant" is not amenable to construction.

2. The Terms "About 1 to 10%" and "About 1-10%" are Not Supported by the Specification and are Indefinite

The claim terms "an amount of about 1 to 10% of at least one additional surfactant" and "about 1-10% of an additional surfactant" lack support in the specification and are indefinite. The Federal Circuit has held that the term "at least about" was invalid for indefiniteness where there was close prior art and there was nothing in the specification and prosecution history that provided any indication as to the scope of the term "about." *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991) ("When the meaning of claims is in doubt, especially when, as is the case here, there is close prior art, they are properly declared invalid."). In *Amgen, Inc.*, the Federal Circuit considered whether the term "at least about 160,000 IU/AU" was indefinite. *Id.* at 1217-18. During prosecution, the initial claims contained the limitation "at least 120,000 IU/AU," which was amended to "at least about 160,000 IU/AU" after the Examiner rejected the claims over a prior art reference's disclosure of 128,620 IU/AU. *Id.* In finding the term "at least about" indefinite, the Federal Circuit concluded that "[b]ecause 'the term 'about' 160,000 gives no hint as to which mean value between the Miyake et al. [*i.e.*, the prior art] value of 128,620 and the mean specific activity level of 160,000 constitutes infringement,' the court held the 'at least about' claims to be invalid for indefiniteness." *Id.*

In the present case, as in *Amgen, Inc.*, the specification and prosecution history of the '427 patent do not provide any indication of the scope of the term "about." *See* Mumper Dec. ¶43. The specification of the '427 patent does not disclose an amount of surfactant below 1% or an amount of surfactant above 10%. *See id.*; Mumper Ex. B. Nor does the '427 patent provide

any disclosure that assists in determining how the scope of the term "about" is to be ascertained in the context of the weight percent of the surfactant. *Id.*; *see* Mumper Dec. ¶44. Instead, the specification merely provides that "the composition contains from 1 to 10% by weight of at least one surfactant." Mumper Ex. B, 4:36-37. The claims as originally filed during prosecution also mirror the scope of the disclosure in the specification in that claim 9 of the originally filed claims recited "[t]he pharmaceutical composition of claim 1, which contains from 1 to 10% by weight of at least one surfactant," without inclusion of the term "about." *See* Mumper Ex. M, claim 9.

During prosecution, the Applicants submitted new claims that recited "an amount of about 1 to 15% of an additional surfactant." *See* Mumper Ex. N. This limitation was amended to recite "an amount of about 1 to 10% of an additional surfactant." *See* Mumper Ex. O, claim 161. In the remarks, however, the Applicants did not provide any guidance or discussion as to the scope or meaning of the term "about 1 to 10% of an additional surfactant." *See* Mumper Dec. ¶44; Mumper Ex. O. Thus, it is clear that like the patent specification and prosecution history in *Amgen, Inc.*, the '427 patent specification and prosecution history do not provide any guidance as to the scope of the term "about." *See Amgen, Inc.*, 927 F.2d at 1217-1218.

Moreover, as in *Amgen, Inc.*, the '427 patent prosecution history also reveals that the prior art is close to the claimed invention. *See id.*; *see also* Mumper Dec. ¶45. After the Applicants amended the claims to narrow the scope from "about 1 to 15%" to "about 1 to 10%, the PTO issued a Notice of Allowance of the claims. *See* Mumper Ex. P. The Notice of Allowance indicates that "[w]hile the prior art of record disclosed all claimed components, the prior art does not disclose the percentages of all the components and the unexpected results." *Id.* at 3. In discussing the prior art of record, the Notice of Allowance specifically identifies U.S. Patent No. 5,993,858 (the "'858 patent") as "[t]he closest prior art of record." *Id.* Not only does

the ’858 patent disclose a surfactant, but the ’858 patent discloses a surfactant in a concentration that is in close proximity to the amount of surfactant set forth in the claims of the ’427 patent. *See* Mumper Dec. ¶45; Mumper Ex. Q, 5:4-7. Specifically, the ’858 discloses compositions comprising a surfactant and co-surfactant and recites that “the range of concentration of the surfactant/co-surfactant broadly ranges from 15 to 90% (v/v).” Mumper Ex. Q, 5:4-7. Thus, the importance of the claim amendment from “about 1 to 15%” to “about 1 to 10%” and the closeness of the prior art is evident from the Notice of Allowance. *See* Mumper Dec. ¶45. Because the specification and prosecution history do not provide any indication as to the scope of the claim terms “about 1 to 10%” and “about 1-10%” in relation to the scope of the prior art that the PTO made clear was close (as it described all of the claimed components but did not disclose the claimed percentages), the term “about” in the ’427 patent cannot be construed. Thus, the term “about” and the claims of the ’427 patent are indefinite, for the same reasons that the term “about” was held to be indefinite in *Amgen, Inc.*, 927 F.2d at 1217-18. Accordingly, Defendants respectfully request that the Court determine that the claim terms “an amount of about 1 to 10% of at least one additional surfactant” and “about 1-10% of an additional surfactant” are not amenable to construction as they are indefinite.

3. In the Event that the Court Determines that these Claim Terms are Construable, the Term “About” Should be Construed Narrowly

While Defendants submit that the terms “an amount of about 1 to 10% of at least one additional surfactant” and “about 1-10% of an additional surfactant” are not amenable to construction as indefinite, if the terms were construable, the most logical meaning would be “an amount of 0.95% to 10.50% of at least one additional excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic.” As set forth above in Section

IV(E)(2), in the context of the alleged invention, particularly given the lack of guidance in the specification and prosecution history, a person of ordinary skill in the art would not be able to ascertain the scope of the term "about." Alternatively, a person of ordinary skill in the art would have considered the term to be narrow in scope – certainly not more than +/- 5% of the recited percentages in the claims. *See* Mumper Dec. ¶¶46-49. That is, a person of ordinary skill in the art would have considered "about 1 to 10%" to mean "0.95% to 10.50%." *Id.*

The term "surfactant" as used in the claims of the '427 patent refers to an excipient that serves a particular function. *See* Mumper Dec. ¶46. Specifically, the parties have agreed that a surfactant means "an excipient that can reduce the interfacial tension between two immiscible phases due to the excipient containing two localized regions, one being hydrophilic in nature and the other hydrophobic." *See* Joint Claim Construction Statement (Dkt. No. 71), Exhibit A; *supra* Section II. Thus, a person of ordinary skill in the art would have understood that the excipient (*i.e.*, the surfactant) is affecting the quality and performance of the formulated composition. *See* Mumper Dec. ¶46. To ensure that the excipient is performing appropriately in the formulated composition, a person of ordinary skill in the art would have understood that the excipient can only be used in a narrow range in which it is known to perform appropriately. *Id.*

At the time of the earliest alleged priority date of the '427 patent, September of 2000, a person of ordinary skill would have been familiar with various FDA Guidance for Industry publications, including the Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls Guidance for Industry ("SUPAC Guidance"). *See* Mumper Dec. ¶47. The SUPAC Guidance "provides recommendations to pharmaceutical sponsors of new drug applications (NDAs), abbreviated new drug applications (ANDAs), and abbreviated antibiotic drug applications (AADAs) who intend to change (1) the components or composition…of a semisolid

formulation during the postapproval period." *Id.*; Mumper Ex. R at 1.

One of the recommendations in the SUPAC Guidance is the likely effect that a change in the amount of excipient would have on a composition and the recommended course of action in such an event. *See* Mumper Dec. ¶48; Mumper Ex. R at 4. The SUPAC Guidance indicates "any change in an excipient up to 5% of approved amount of that excipient" is "unlikely to have any detectable impact on formulation quality and performance." Mumper Ex. R at 6. A change in an excipient above this level (*i.e.*, "changes of >5% and ≤10% of approved amount of an individual excipient"), however, "could have a significant impact on formulation quality and performance." *Id.*; *see* Mumper Dec. ¶48. Thus, a person of ordinary skill would have considered a variance in greater than 5% of an excipient as one that could have a significant impact on the composition. *See* Mumper Dec. ¶49. Therefore, a person of ordinary skill would have considered any change of greater than 5% to be a significant alteration. *See id.* Accordingly, the term "about" as used in the '427 patent should not be construed to encompass subject matter beyond a 5% variance (*i.e.*, 0.95% to 10.5%). Therefore, if the Court determines that the claims terms "an amount of about 1 to 10% of at least one additional surfactant" and "about 1-10% of an additional surfactant" are amenable to construction, Defendants respectfully request that the Court adopt their proposed construction.

G. "About 10–20 mg of the Composition" ('427 Patent, Claim 10)

Defendants submit that there is no need to construe this claim term, because doing so has no bearing on the issues of infringement and invalidity. Defendants' isotretinoin capsules are produced in four dosage forms: 10, 20, 30, and 40 mg. The relationship between any particular dosage form and the 10–20 mg range stated in the claim limitation is plainly apparent. Plaintiffs' proposed construction does not change any basis for applying this claimed range to Defendants'

products, because it neither shrinks nor extends the range to cover different products than would be covered absent the claim construction. As a result, Plaintiffs' construction—if adopted by the Court—would not affect any aspect of the ultimate infringement controversy between the parties. Nor does Plaintiffs' proposed construction impact the resolution of Defendants' invalidity contentions. Isotretinoin was long-known to be effective at a 10–20 mg dosage range. In consequence, neither the claim limitation nor the Plaintiffs' proposed construction confers novelty or patentability to the claims.

When a court considers "claim construction issues that do not actually affect the infringement controversy between the parties," the subsequent analysis constitutes an advisory opinion. *See Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1336 (Fed. Cir. 2008). Such advisory opinions are impermissible. *See id.* ("The Supreme Court has explicitly held that Article III does not permit the courts to resolve issues when it is not clear that the resolution of the question will resolve a concrete controversy between interested parties."). Plaintiffs' proposed claim construction also does not affect invalidity issues, and thus the *Jang* rationale may be extended to the controversy over invalidity. Because the construction of this term would not resolve any issue implicated in the parties' infringement or invalidity contentions, it is clear that any construction thereof would amount to an advisory opinion. Therefore, Defendants respectfully submit that the Court should reject Plaintiffs' attempts to seek an advisory opinion and decline construing the term "about 10-20 mg of the composition."[10]

V. CONCLUSION

For the reasons stated herein, Actavis respectfully requests that the Court adopt Actavis' proposed constructions of the disputed claim terms.

[10] If Plaintiffs provide a rationale for construing this term in their opening brief, Defendants reserve the right to respond accordingly in their responsive claim construction brief.

Date: November 14, 2014

s/ Liza M. Walsh

Liza M. Walsh
Tricia B. O'Reilly
Eleonore Ofosu-Antwi
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
Telephone: (973) 535-0500
Facsimile: (973) 535-9217

E. Anthony Figg
C. Nichole Gifford
Lisa N. Phillips
Brett A. Postal
ROTHWELL, FIGG, ERNST & MANBECK
607 14th Street, NW, Suite 800
Washington, DC 20005
(202) 783-6040 (telephone)
(202) 783-6031 (facsimile)

Attorneys for Defendants Actavis Laboratories FL, Inc., Andrx Corp., Actavis, Inc. and Actavis Pharma, Inc.